MEMORANDUM

SUBJECT: REGISTRATION OF PERMETHRIN FOR MILITARY USES
(HED PROJECT #9-1356)

TO: G. LaRocca, PM 15
Insecticide and Rodenticide Branch
Registration Division (H7505C)

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Health Effects Division (H7509C)

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Non-Dietary Exposure Branch
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THRU: Charles L. Trichilo, Ph.D., Chief
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Please find below the NDEB review of ....

HED Project #: 9-1356

RD or SRRD Record #: 50404L

Caswell #: 652BB

Date Received: 04/26/89    Review Time: 2 days

Date Returned: 07/31/89

Deferral to: ______ Biological Analysis Branch/BEAD

Science Analysis & Coordination Branch

TE - Insecticide/Rodenticide Support Section:

TE - Herbicide Fungicide Antimicrobial Support Section
1.0 INTRODUCTION

Coulston International Corporation has submitted on behalf of the U.S. Army Research Development and Engineering Center, additional information in support of the registration of permethrin for use on Battle Dress Uniforms (BDUs). The additional information is in response to the September 23, 1990 review of the registration request by L. Kutney (R&D Project No. 8-1077A).

The product in question contains 0.5% permethrin as the active ingredient. It is packaged in a 6 oz aerosol and is intended to repel or kill ticks, mosquitoes, and chiggers. According to RD, the material is already registered for civilian use as the product Permanone. The military is seeking a separate registration for use in the field by uniformed members of the Armed Services.

Fairfield America has submitted on behalf on the Department of Defense (DOD) a request to register Perigen Industrial Mothproof. Perigen contains 12% permethrin as the active ingredient and is currently registered for civilian use according to RD. The DOD would like to use Perigen to impregnate military wool and wool-blend fabrics.

2.0 CONCLUSION

The Nondietary Exposure Branch (NDEB) estimates that the dermal exposure from wearing permethrin treated BDUs will average 0.0056 mg/kg/day and total 2.0 mg/kg/year for a 70 kg individual. The estimates are not adjusted for the dermal absorption of permethrin (assumes 100% absorption) and are based on the unlikely scenario of an individual wearing the BDU for 24 hours/day and for 365 days/year. These estimates assume that only 4 percent of the permethrin in BDUs will migrate to the skin; however, NDEB defers to MB-TPS review and evaluation of this assumption derived from a rabbit study (MBID No. 607568-17).

Exposure to Perigen-treated cots and other nonclothing fabrics is assumed to be even less than to that received wearing permethrin-treated clothing.

3.0 DISCUSSION

The proposed permethrin aerosol contains (0.5% x 6 oz x 28,000 mg/oz) 840 mg permethrin. Based on proposed label directions, 75 percent of the contents are to be applied to BDUs and the remaining 25 percent to mosquito netting. Therefore, 630 mg permethrin are applied to BDUs. Coulston has determined
that the surface area of a BDU is 57,200 cm². When one assumes
that approximately half (the inner surface) is in contact with
the skin, the total surface area of a BDU contacting the skin is
28,600 cm². If the entire 630 mg permethrin were to adhere to
the BDU, the concentration of permethrin on the BDU available for
skin contact would be 0.022 mg/cm².

The Army field tested the aerosol can applications in the
Everglades between April 28 and May 8, 1988 (Attachment C of
Coulston February 23, 1989 submission). The RDUs averaged 0.027-
mg permethrin/cm² as measured by gas chromatography. NDPR will
utilize the field measurement in its calculations. Attachment C
also provides permethrin concentrations on RDUs after laundering.
The concentrations were as follows:

<table>
<thead>
<tr>
<th>Launderings</th>
<th>Permethrin (mg/cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.027</td>
</tr>
<tr>
<td>2</td>
<td>0.015</td>
</tr>
<tr>
<td>5</td>
<td>0.009</td>
</tr>
<tr>
<td>10</td>
<td>0.007</td>
</tr>
</tbody>
</table>

Based on the proposed label, the RDUs are retreated every sixth
week after six launderings. Coulston states the average field
lifespan of a BDU is 120 days.

The surface area of a 70 kg adult male is 17,420 cm² for
the arms, legs, and torso (Subdivision II, Pesticide Assessment
Guidelines). Based on the laundering data, a maximum total of
0.020 mg/cm² would be available after 12 launderings (0.027
mg/cm² at application minus 0.007 mg/cm² after 10 launderings
equals 0.020 mg/cm² available). The permethrin available would
actually be less after six launderings. Based on the 0.020
mg/cm² permethrin not retained in the BDU and a skin contact area
of 17,420 cm², a total of 348 mg permethrin can potentially be
available for dermal absorption over the 6-week period prior to
reapplication. For a 70 kg individual, the average daily
potential exposure would be (348 mg/42 days x 1/70 kg) 0.12
mg/kg/day over the first 6-week period.

After 6 weeks, the BDU would be retreated at 0.027 mg/cm²
which added to the prior treatment residues of approximately
0.008 mg/cm² after six launderings would yield an initial second
treatment residue level of 0.035 mg/cm². The laundering data
indicated that 74 percent of the 0.027 mg/cm² was removed after
10 launderings. If one assumes that 74 percent of the 0.035
mg/cm² residue level is removed and all is available for dermal
absorption, then 0.026 mg/cm² is available. Based on 0.026
mg/cm² not retained in the BDU during the second 6-week period
and a skin contact area of 17,420 cm², a total of 453 mg
permethrin can potentially be available for dermal absorption. For the 70 kg individual, the average daily exposure over the second 6-week period would be (453 mg/42 days x 1/70 kg) 0.15 mg/kg/day.

At the end of the second 6-week period, the BDU would have retained 0.009 mg/cm² permethrin residues. The third and final spray application of 0.027 mg/cm² added to the 0.009 mg/cm² would yield an initial third 6-week period residue level of 0.036 mg/cm². Again assuming 74 percent of the residues are removed, a total of 0.027 mg/cm² would be available for potential exposure. The average daily exposure over this third 6-week treatment period would be 0.16 mg/kg/day. The overall potential daily amount of permethrin available for exposure over the three-treatment, 120-day life of the BDU would average 0.14 mg/kg/day. This three-spray cycle for a BDU could be repeated twice more during one year. An individual wearing three BDUs over a 1-year period would have a potential dermal exposure of 51 mg/kg/year assuming all permethrin not retained after laundering is available for dermal exposure.

The average daily amount of permethrin available for dermal exposure of 0.14 mg/kg/day is probably an overestimate of the actual amount leaching from the BDU onto the skin. The vast majority of the permethrin removed from BDUs may be removed during laundering. A study submitted by the registrant (Snodgrass, H.L., U.S. Army Environmental Hygiene Agency, 1988, Mitigation of Permethrin From Impregnated Military Fabrics as Measured in Rabbits, MRID No. 40766R-13) concluded that 4 percent of the permethrin in treated military dress fabric migrated to rabbit skin. NDPB defers review of this rabbit study by Toxicology Branch T-IPS. If it is assumed that 4 percent of the permethrin not retained by the fabric migrates to the skin of the wearer (conversely, 96 percent of the nonretained permethrin is either removed during laundering or lost through other processes), the total dermal exposure to permethrin in BDUs would be (0.14 mg/kg/day x 0.04) 0.0056 mg/kg/day or 2.0 mg/kg/year for 365 days.

cc: Circulation
SACF (Linda Kutney)
Permethrin File
Correspondence File